09/079,569



UNITED STATES EPARTMENT OF COMMERCE Patent and Trademark Office

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APPLICATION NUMBER FILING DATE FIRST NAMED APPLICANT ATTORNEY DOCKET NO.

09/079.589 05/14/98 HOYLE W A-45/11/
EXAMINER

HM21/0915
U.S. PATENT OPERATIONS REW DEPT 430 M S 27 4 A
AMGEN INC.
ONE AMGEN CENTER DRIVE

AMGEN INC ONE AMGEN CENTER DRIVE	DATE MAILED	
THOUSAND OAKS CA 91320-1789		09/15/98
This is a communication from the examiner in charge of your application.		0.37 1.07 50
COMMISSIONER OF PATENTS AND TRADEMARKS		
NOTICE OF ALLOWA	BILITY	•
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate	CLOSED in this application. If not communication will be mailed in du	included herewith (or ue course.
☐ This communication is responsive to		·
A The allowed claim(s) is/are 22-24 renumbered as do	aims 1-3 respective	il yr.
☐ The drawings filed on are acceptable.		
Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 1	19(a)-(d).	
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority docum	nents have been	
received.		
received in Application No. (Series Code/Serial Number)		
$\hfill\Box$ received in this national stage application from the International Bureau (F	PCT Rule 17.2(a)).	
*Certified copies not received:		 '
☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §	§ 119(e).	
A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the req FROM THE "DATE MAILED" of this Office action. Failure to timely comply will re time may be obtained under the provisions of 37 CFR 1.136(a).	uirements noted below is set to EXI sult in ABANDONMENT of this app	PIRE THREE MONTHS lication. Extensions of
☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL A declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQU		closes that the oath or
Applicant MUST submit NEW FORMAL DRAWINGS		
because the originally filed drawings were declared by applicant to be infor	rmal.	
including changes required by the Notice of Draftperson's Patent Drawing	Review, PTO-948, attached hereto	or to Paper No
 including changes required by the proposed drawing correction filed on by the examiner. 	, wh	ich has been approved
including changes required by the attached Examiner's Amendment/Comm	nent.	
Identifying indicia such as the application number (see 37 CFR 1.84(c)) so The drawings should be filed as a separate paper with a transmittal letter	hould be written on the reverse s r addressed to the Official Draftpe	ide of the drawings. erson.
☐ Note the attached Examiner's comment regarding REQUIREMENT FOR TH	E DEPOSIT OF BIOLOGICAL MAT	ERIAL.
Any response to this letter should include, in the upper right hand corner, the AP If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE B ALLOWANCE should also be included.		
Attachment(s)		
Notice of References Cited, PTO-892		
Information Disclosure Statement(s), PTO-1449, Paper No(s).		
Notice of Draftsperson's Patent Drawing Review, PTO-948		
☐ Notice of Informal Patent Application, PTO-152		
☐ Interview Summary, PTO-413		
Examiner's Amendment/Comment		
Examiner's Comment Regarding Requirement for Deposit of Biological Ma	iterial	
Examiner's Statement of Reasons for Allowance		
PTOL-37 (Rev. 10/95)		"U.S. GPO: 1997-422-194/60002



UNITED STATES DEPARTMENT OF COMMERCE **Patent and Trademark Office**

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM21/0915

U S PATENT OPERATIONS RBW DEPT 430 M S 27 4 A AMGEN INC ONE AMGEN CENTER DRIVE THOUSAND DAKS CA 91320-1789

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AN	D GROUP ART UNIT		DATE MAILED
09/079,58	59 05/14/98	003	BUDENS, R		1648	09/15/98
First Named Applicant BOYLE.		WIL	LIAM J.			
		WIT.	L. L (A) 14			
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ILE OF VENTION DISTEOPROTI	EGENIN BINDI	IG J∕R OTEINS				
ILE OF VENTION DISTRICT ROTT	CLASS-SUBCLASS	BATCH NO.		ALL ENTITY FEE 0	DUE .	DATE DUE

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

435-007.240

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THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. A SECOND OF THE STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

A-451D

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- I. Review the SMALL ENTITY status shown above. If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
 - A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
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If the SMALL ENTITY is shown as NO:

UTILITY

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

- II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.
- III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PATENT AND TRADEMARK OFFICE COPY

PTOL-85 (REV. 10-96) Approved for use through 06/30/99. (0651-0033)

Serial No. 09/079,569 Art Unit 1648

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EXAMINER'S REASONS FOR ALLOWANCE

The following is an Examiner's Statement of Reasons for Allowance:

Applicant's invention is directed to antibodies which bind osteoprotegerin binding protein (OBP) and a method of detecting OBP using these antibodies. Applicant is the first to identify and characterize OBP (see parent application 08/842,842) and, given the knowledge of OBP as taught by applicant, it would be well within the level of skill of one of ordinary skill in the art to use OBP to produce an antibody which could be used in well known immunoassay methods. novelty of the claimed invention resides in the identification and characterization of the OBP itself. Applicant appears to be the first inventor of OBP as disclosed in allowed parent application Serial No. 08/842,842. Lacey et al. (R) discloses osteoprotegerin ligand which appears to be identical to the instant OBP. Lacey et al. includes as coauthor applicant Boyle. Lacey et al. further discloses that OBP appears to be identical to the TRANCE protein of Wong et al. (S) and the RANK protein of Anderson et al. (T). However, the instant application is accorded benefit of the earlier filing date of parent application Serial No. 08/842,842, filed April 16, Therefore, Wong et al. and Anderson et al. do not 1997. constitute prior art to the instant application. Applicant is the first to identify OBP. Methods for making antibodies and for using such antibodies in assays detecting the corresponding antigens are well known and routinely used in the art once the antigen, i.e., OBP, has been identified. Therefore, the claimed invention is deemed to distinguish over the art.

Any comments considered necessary by applicant must be

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submitted no later than the Payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

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Papers relating to this application may be submitted to Group 1600 by facsimile transmission. The Fax number is (703) 308-4242. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robert D. Budens at (703) 308-2960. The Examiner can normally be reached Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Don Adams, can be reached at (703) 308-0570.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0196.

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Robert D. Budens Primary Examiner Art Unit 1648

rdb September 14, 1998

08/079,569 Dielog 9/3/98

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Set	Items	Description
S1	125	E13, E14, E15, E31,E32
S2	16	AU="BOYLE WILLIAM J":AU="BOYLE WILLIAM JOSEPH JR"
S3	140	S1 OR S2
S4	37	OSTEOPROTEG?
S5	8	S3 AND S4
S6	29	S4 NOT S5
S7	18	RD (unique items)
S8	39	(OCIF? OR OSTEOCLASTOGEN?(1W)INHIBIT?)
S9	21	S8 NOT (S5 OR S6)
S10	13	RD (unique items)
S11	1049	(ODF? OR OSTEOCLAS?(1W)DIFFERENT?)
S12	1029	S11 NOT (S5 OR S6 OR S8)
S13	24	S12 AND ((ANTIBOD? OR IMMUNOGLOB? OR ANTISER?)(2N)(ODF? OR
	(C	STEOCLAS?(1W)DIFFERENT?)))
S14	12	RD (unique items)

=> d his

L10

(FILE 'USPAT' ENTERED AT 13:54:02 ON 03 SEP 1998)

	,		
		E	E BOYLE, WIL?/IN
L1		30 S	S E11-E13
L2		0 5	S OSTEOPROTEG?
L3		0 5	F PROTEGER?
L4		71 S	G OPG
L5		0 5	G L1 AND L4
L6		16 9	S L1 AND BONE?
L7		0 9	S L6 AND OSTEOCLA?
L8		72 5	S OSTEOPRO?
T.9		0.9	S I.6 AND I.8

8 S OSTEOPROT?

09/079,569 Dialos 9/3/98